

RESPONSE

The Examiner's objections with respect to the recitation of the final element of claims 15 and 21 has been traversed for these dependent claims by amending the language in claims 15 and 21 and by amending the claims dependent from claim 21, specifically claims 22 and 23 to overcome the § 112 rejections. Applicants also submit that at least claims 16, 17, 18, 19, 20, 22, 23, and 24 should be allowable in independent form even if the rejections as to claim 15 and 21 are maintained.

The Examiner questions whether or not the presently claimed invention could be practiced without "undue experimentation." In the previously pending claims, the Examiner construes the claims such that the method must successfully diagnose Down Syndrome by identifying reproducible chemical factors that predict the presence of the disease. However, the present invention is addressed to using the differences between a control profile and with sample, as one indication of disease. Thus, the claimed method does not depend on a demonstration answering the question of whether or not the method can be practiced by analyzing any particular metabolite with a mathematical formula that is predetermined to diagnose the specific disease of Down Syndrome based on any particular metabolite. As claimed, the invention compares a sample with a control profile, notes the differences, and then compares the different values to a disease profile. Because chromosomal abnormalities are complex, one cannot predict that certain anomalies in metabolite concentrates will always present in precise ratios or at particular times. Thus, applicants have amended the final method step to specify that the differences that are revealed by the measurements provided by the claimed method are used in a comparison to a profile that would be present in Down Syndrome in a fetus-- no explicit

prediction of a diagnosis is necessary. Therefore, no doubt can remain as to whether or not the invention is enabled as claimed because one of ordinary skill in the art certainly actually perform the method as claimed without undue experimentation based on conducting those steps that the Examiner has already indicated are enabled and the requirement for a perfectly predictive diagnosis method is eliminated

As claimed, a physician or diagnostician who analyzes clinical conditions based on biochemical testing could identify the presence of a markers present in a disease condition based on a number of individual measurements of underlying biochemical mechanisms. On this particular point, no experimentation is required, rather the skilled judgment of one of ordinary skill in the art as described in the specification.

Therefore, each of the grounds of rejection in the Office Action are overcome by the foregoing amendments.

### CONCLUSION

By entry of this Amendment, Applicant respectfully submits that all of the Examiner's rejections have been overcome. Additionally, the Examiner is invited to telephone the undersigned representative if the Examiner believes that a telephonic interview would advance this case to allowance.

The Commissioner is authorized to charge a three-month extension fee of \$510.00 to Orrick Herrington & Sutcliffe's Deposit Account No. 150665 and any additional fees required by the filing of these papers, and to credit any overpayment to Orrick Herrington & Sutcliffe's Deposit Account No. 150665.

Respectfully submitted,

ORRICK, HERRINGTON & SUTCLIFFE LLP

Dated: December 11, 2006

By: 

Kurt T. Mulville, Reg. No. 37,194

4 Park Plaza, Suite 1600  
Irvine, CA 92614  
949/567-6700 X 7740 Telephone  
949/567-6710 Facsimile